

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-630V

Filed: January 11, 2018

DIANE SCOTT,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Finding of Fact; Special Processing
Unit (SPU); Ruling on Entitlement;
Causation-In-Fact; Influenza (Flu)
Vaccine; Shoulder Injury Related to
Vaccine Administration (SIRVA)

*Jeffrey S. Pop, Jeffrey S. Pop & Associates, Beverly Hills, CA, for petitioner.
Adriana Ruth Teitel, U.S. Department of Justice, Washington, DC, for respondent.*

RULING ON ENTITLEMENT¹

Dorsey, Chief Special Master:

On May 26, 2016, Diane Scott (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, et seq. (the “Vaccine Act” or “Program”). The petition alleges that following the administration of an influenza (“flu”) vaccine on October 18, 2013, petitioner developed a shoulder injury related to vaccine administration (“SIRVA”). Pet. at 1. The case was assigned to the Special Processing Unit (“SPU”).

I. Procedural History

On May 26, 2016, petitioner filed a petition for compensation under the Vaccine Act alleging that, following an October 18, 2013 flu vaccination, she developed

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

immediate left shoulder pain. Pet. at 1-2. On June 3, 2016, petitioner filed exhibits 1-6, which consisted of medical records and petitioner's declaration, and updated records on June 20, 2017.

On July 12, 2016, an initial status conference was held with the staff attorney managing this case. During the status conference, it was noted that there appeared to be a gap of approximately one year between when petitioner first sought medical treatment for her injury and when she next reported the injury was unresolved. ECF No. 11, Scheduling Order, dated July 12, 2015.

On October 31, 2016, respondent filed a report pursuant to Vaccine Rule 4(c) stating this case was not appropriate for compensation under the terms of the Vaccine Act for numerous reasons. ECF No. 15, Resp. R. 4(c) Rpt. at 2, 9. Respondent argued petitioner did not establish she suffered the residual effects or complications of her injury for six months after the administration of the vaccine, citing the lack of contemporaneous records. *Id.* at 6. Respondent also argued petitioner failed to establish petitioner's shoulder injury was related to vaccine administration. *Id.* at 8-9. Respondent further stated that the "record fails to establish by preponderant evidence that petitioner suffered a shoulder injury related to vaccine administration." *Id.* at 8.

A Rule 5 status conference was held on November 30, 2016, to address (i) the date and location of vaccination, (ii) the severity of injury, and (iii) causation. The undersigned informed the parties that she reviewed the records and found preponderant evidence to support a tentative finding that this case meets the criteria for a SIRVA. ECF No. 16, Order dated Dec. 13, 2016. The undersigned acknowledged that respondent might not elect to concede the causation claim, but strongly encouraged the parties to pursue litigative risk settlement discussions. *Id.* at 4.

Following the Rule 5 status conference and December 13, 2016 Order, the parties began settlement negotiations. Petitioner stated that an initial demand was communicated to respondent on January 9, 2017. ECF No. 17. However, on March 10, 2017, respondent stated in a status report that he has further considered the filed evidence in this case but has not changed his prior position that the case does not support engaging in settlement discussions. ECF No. 23.

A status conference on April 7, 2017 was held to address the status of settlement negotiations. ECF No. 25, Order dated Apr. 10, 2017. Respondent stated that the record does not establish that petitioner suffered residual effects or complications of the injury for six months and that petitioner failed to establish her shoulder injury was related to a covered vaccine. *Id.* Petitioner was ordered to file any additional evidence including relevant affidavits and an amended Statement of Completion. *Id.* Respondent was ordered to file a status report stating how she wanted to proceed in this case. *Id.*

Petitioner filed additional evidence, including a vaccination record on April 7, 2017 (Pet. Ex. 8), an affidavit from her ex-husband on May 22, 2017 (Pet. Ex. 9), and an affidavit from a coworker on June 5, 2017 (Pet. Ex. 10). Petitioner subsequently

completed the record and filed her statement of completion on June 5, 2017. ECF No. 29 Statement of Completion.

Respondent filed a status report on July 5, 2017 stating her position regarding engaging in settlement discussions is unchanged and believes a fact hearing may be necessary. ECF No. 31, Resp. Status Rpt. dated July 5, 2017.

On July 20, 2017, a status conference was held with both parties stating they would be amenable to a ruling on the record in the alternative to a fact hearing, but indicated a desire to submit additional briefing. Both parties were ordered to submit briefs of proposed findings of facts and conclusions of law no later than August 23, 2017. ECF No. 32, Order dated July 24, 2017. On August 23, 2017, petitioner filed Petitioner's Brief of Proposed Findings of Fact and Conclusions of Law (ECF No. 34) and respondent filed Respondent's Memorandum and Proposed Factual Findings ("Res. Mot.") (ECF No. 33).

II. Fact History

On October 28, 2013, petitioner received an intramuscular Fluzone influenza ("flu") vaccination in her left deltoid at Walgreens Pharmacy. Pet. Exs. 8 at 1; 11 at 3. Prior to petitioner's flu vaccination, her records indicate she had various medical concerns that were unrelated to left shoulder pain, including a right knee injury in October of 2012 (Pet. Ex. 3 at 1-6) and cholecystitis that necessitated surgery in November of 2012 (Pet. Ex. 3 at 6-8, Pet. Ex. 8 at 15-19).

Petitioner sought medical care on December 6, 2013 from Dr. Veronica Mardo due to left arm pain. Pet. Ex. 3 at 9. Petitioner reported that she "had a flu shot at Walgreens on October 18 and she stated that she was given the injection higher up close to the humeral head" and "that the arm has been hurting since then." *Id.* Petitioner was diagnosed with tendonitis. *Id.* at 11. Petitioner was advised to take over-the-counter pain medication twice a day for five days and to restrict heavy lifting. *Id.* at 11.

Petitioner was seen multiple times for unrelated medical issues between December of 2013 and November of 2014. On January 30, 2014, petitioner visited her doctor, complaining of body aches, headaches, nausea, and a low grade fever for four days and was diagnosed with bronchitis. Pet. Ex. 3 at 12-14. On February 24, 2014, petitioner had an annual gynecological exam. *Id.* at 18. On April 7, 2014, petitioner was seen for a persistent cough. Petitioner was seen again for respiratory concerns multiple times between late April and August of 2014, and was eventually diagnosed with bronchitis, asthma, benign neoplasm, and a sebaceous cyst. *Id.* at 19-40; 48-67. On July 15, 2014, petitioner had a routine physical. *Id.* at 41. During these visits, there is no record that an examination of petitioner's left shoulder occurred, however there is also no record that she complained of shoulder pain.

On November 20, 2014, Petitioner visited her primary care physician, Dr. John Tedesco, complaining of left shoulder pain. Pet. Ex. 3 at 68. Petitioner reported that she received a flu shot in her left shoulder a year ago that “seemed to be very high on the posterior shoulder and it was very painful.” Petitioner also stated that her shoulder has remained painful and had gotten progressively weaker. *Id.* Upon examination, Dr. Tedesco reported petitioner’s left shoulder had a limited range of motion that was also painful, and weakness on internal and external rotation. *Id.* at 70. Petitioner was assessed with joint pain and rotator cuff disorder. *Id.* Petitioner was prescribed pain medication and referred to physical therapy. *Id.* at 71.

On November 26, 2014, Petitioner began physical therapy for her left shoulder. Pet. Ex. 7 at 1-35. Petitioner stated that she was injured when she received a flu shot in October of 2013, stating that the shot was given too high, and her injection “was done just under the acromion.” *Id.* at 1. Petitioner’s physical therapy visit on December 22, 2014 reported a decrease in overall pain in daily activities allowing petitioner to resume household chores with her left arm. *Id.* at 35.

On December 30, 2014, Petitioner visited Dr. Tedesco for a follow-up exam and reported that she had been doing therapy for her shoulder, which she reported was improving. Pet. Ex. 3 at 72.

On August 31, 2015, Petitioner returned to see Dr. Tedesco for her ongoing left shoulder pain, and reported that her left shoulder was still painful, and woke her at night. Pet. Ex. 3 at 96. Petitioner stated she was doing at home physical therapy exercise, but her shoulder was not improving. *Id.* Petitioner was referred to an orthopedist at the Florida Orthopaedic Institute. *Id.* at 99.

Petitioner met with Dr. Mark Mighell, MD, at the Florida Orthopaedic Institute on September 8, 2015, and described her chronic history of left shoulder pain since a flu shot.² Pet. Ex. 5 at 1. Dr. Mighell assessed petitioner with left shoulder adhesive capsulitis and administered a corticosteroid injection. *Id.* at 2. Petitioner underwent physical therapy between September 22, 2015 and October 29, 2015. *Id.* at 13. On October 20, 2015, petitioner’s physical therapy report states that she “initially made good improvements in overall range of motion but has plateaued in recent weeks.” Pet. Ex. 5 at 23.

On November 2, 2015, Petitioner returned to Dr. Tedesco for injuries related to a vehicle accident. Pet. Ex. 3 at 107. Petitioner reported that her left shoulder was finally better. *Id.* However, Petitioner returned to Dr. Mighell for corticosteroid injections on October 20, 2015 and December 29, 2015 due to left shoulder pain. Pet. Ex 5 at 3-4.³

² This record indicates petitioner’s left shoulder pain began on December 18, 2013, however this appears to be a mistake as she first sought treatment for pain in her left shoulder on December 6, 2013. Pet. Ex. 3 at 9.

³ Petitioner’s briefing states that petitioner received a fourth corticosteroid injection from Dr. Mighell on November 29, 2016, however there is no record of event. Pet. Mot. at 7.

In addition to the medical records, petitioner submitted three affidavits in support of her petition: Declaration of Diane Scott (Pet. Ex. 1), Affidavit of Todd Scott (Pet. Ex. 9), and Affidavit of Tammi Burns (Pet. Ex. 10).

In petitioner's affidavit, she states that she received a flu vaccine on October 18, 2013, and that the flu vaccination was placed very high on her left shoulder. Pet. Ex. 1. Further, petitioner states that the flu vaccine caused "immediate left shoulder pain" and she began taking Motrin daily as a result. *Id.* Petitioner stated that, following a diagnoses of tendonitis on December 6, 2013, she began taking naproxen. *Id.* at 2. However, pain in her left shoulder returned gradually, which she treated with over-the-counter pain medication. Petitioner reported that she was unable to seek further treatment for her shoulder pain until November 20, 2014, because she was the sole supporter of her family. *Id.* Petitioner also stated that she was unable to seek professional treatment after December 30, 2014, due to financial limitations and a serious medical issue involving her daughter that took priority over her shoulder. *Id.*

Todd Scott, petitioner's ex-husband, submitted an affidavit on petitioner's behalf. Pet. Ex. 9. Mr. Scott stated that both he and petitioner received flu vaccinations on the same day in October of 2013. *Id.* at 1. Further, Mr. Scott stated that petitioner began complaining of shoulder pain almost immediately after receiving the vaccination. *Id.* Mr. Scott further stated that, after seeing her doctor, petitioner was told to "wait it out and that the pain would go away", however over the next year petitioner continued to complain about shoulder pain. *Id.* at 2.

Tammi Burns, a former co-worker of petitioner, also submitted an affidavit on petitioner's behalf. Pet. Ex. 10. Ms. Burns stated that she recalls petitioner complaining of pain in her left shoulder that began "right after receiving the flu shot at a pharmacy." *Id.* at 1. Ms. Burns also stated petitioner showed her that she had limited mobility in her left arm, and that she would complain about her left shoulder pain for the next several years. *Id.* at 2.

III. Applicable Legal Standards

Under the Vaccine Act, a petition for compensation must contain "supporting documentation, demonstrating that the person who suffered [a vaccine related injury] ... suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine." 42 U.S.C. § 300aa-11(c)(1)(D)(i). The burden of establishing, by a preponderance of the evidence, the persistence of a vaccine-caused injury for longer than six months is borne by petitioners. *Song v. Sec'y of Health & Human Servs.*, 31 Fed. Cl. 61, 65-66, *aff'd*, 41 F.3d 1520 (Fed.Cir.1994).

Under the Vaccine Act, petitioner may prevail on her claim if she has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth

in the Vaccine Injury Table (the “Table”). 42 U.S.C. § 300aa–11(c)(1)(C)(i).⁴ If petitioner establishes that she has suffered a “Table Injury,” causation is presumed.

If, however, petitioner suffered an injury that is not listed in the Table, referred to as “non-Table or [an] off-Table” injury, the petitioner must show that she received a vaccine covered by the Program, 42 U.S.C. §300aa–14(a); that she sustained an injury that was caused-in-fact by the vaccine or had an injury significantly aggravated by the vaccine, *and* that she either “(i) suffered the residual effects or complications of such [vaccine-related] illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or ... (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]” 42 U.S.C. §300aa–11(c)(1)(D).

In alleging an off-Table injury, to prevail petitioner must prove her case “by a preponderance of the evidence,” 42 U.S.C. §300aa–13(a)(1)(A), and a finding cannot be made based upon unsupported claims of the petitioner alone. 42 U.S.C. §300aa–13(a)(1). This standard is “one of . . . simple preponderance, or ‘more probable than not’ causation.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec’y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993)). The Federal Circuit has held that to establish an off-Table injury, petitioner must “prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir. 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioner “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. See 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing

⁴ The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. 42 U.S.C. § 300aa-14(a).

of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

IV. Analysis

Petitioner alleges that she developed a SIRVA following an October 18, 2013 flu vaccination. Petitioner developed a shoulder injury related to vaccine administration ("SIRVA"). Pet. at 1. Further, petitioner alleges that her SIRVA continued from the time she received the flu vaccination until now, stating that while petitioner's range of motion has improved, she still has difficulty and pain reaching behind her back. Pet. Mot. at 7.

Respondent opposes compensation in this case, arguing that there is no persuasive evidence to conclude that the shoulder pain petitioner reported continued, without interruption, throughout 2014. Because petitioner has not established that she meets the six-month sequelae requirements set forth in 42 U.S.C. § 300aa-11(c)(1)(D)(i), respondent recommends that this case be dismissed. Res. Mot. at 10.

The undersigned finds petitioner has provided evidence sufficient to establish that she received the alleged vaccination, and that the vaccination caused her to suffer a SIRVA. Specifically, petitioner has satisfied the three *Althen* prongs: (i) petitioner has provided sufficient evidence to establish a medical theory of causation; (ii) petitioner has set forth a logical sequence of cause and effect showing the vaccination caused her alleged injuries; and (iii) petitioner has established a proximal temporal relationship between the vaccination and the alleged injuries.

A. The Elements of Petitioner's SIRVA Claim

Effective for petitions filed beginning on March 21, 2017, a SIRVA is an injury listed on the Vaccine Injury Table ("Table"). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner's claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned's findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder

in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

Id.; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, Shoulder injury related to vaccine administration (SIRVA), Vaccine 28(51):8049-8052) filed as Court Exhibit I.

a. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.

The undersigned reviewed petitioner's medical history prior to her October 18, 2013 vaccination. Her medical records show she was seen for medical problems unrelated to shoulder pain, including a knee injury and cholecystitis in the fall of 2012. See Pet. Ex. 3 at 6-8 and Pet. Ex. 8 at 15-19. Only after petitioner received a flu shot did she complain of left shoulder pain. Petitioner's shoulder pain was first recorded on December 6, 2013 but was reported as having started when she received the flu shot. Pet. Ex. 3 at 9.

For these reasons, the undersigned finds that petitioner had no history of pain, inflammation or dysfunction of the affected shoulder prior to her flu vaccine administered on October 18, 2013. Further, the vaccination would explain the symptoms and exam findings that occurred after petitioner's vaccination.

b. Onset occurred within the specified time frame.

Based on the medical records and affidavit evidence, the undersigned finds a temporal relationship between petitioner's October 18, 2013 flu shot and the SIRVA. Multiple records show that petitioner received an intramuscular flu vaccination in her left deltoid at Walgreens Pharmacy on October 18, 2013. Pet. Exs. 8 at 1; 11 at 3. Petitioner also reported arm pain on December 6, 2013, and stated that her arm had been hurting since she received her flu shot. Pet. Ex. 3 at 9. Additionally, petitioner consistently stated pain in her left shoulder started immediately after she received a flu shot on October 18, 2013. See Pet. Ex. 2 at 1; Pet. Ex. 3 at 9, 68, 72-74; Pet. Ex. 4 at 1. This is consistent with the interval of onset set forth in the table for a SIRVA claim. 42 C.F.R. § 100.3.

Petitioner's affidavit evidence supports the onset date of her shoulder pain. For example, petitioner's ex-husband, Mr. Scott, stated that petitioner began complaining of shoulder pain almost immediately after receiving her vaccination. Pet. Ex. 9 at 1. Petitioner's former coworker, Ms. Burns, also reported that petitioner complained of left

shoulder pain that began “right after receiving the flu shot at a pharmacy.” Pet. Ex. 10 at 1.

Thus, the undersigned finds that the onset of petitioner’s pain occurred within 48 hours of the October 18, 2013 flu vaccination.

c. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.

The records and affidavit evidence indicate that petitioner received a flu vaccine in her left shoulder. Petitioner’s insurance claim states that petitioner received an immunization on “10/18/2013”. Pet. Ex. 2 at 1. Petitioner also submitted proof of vaccination indicating she received a vaccination on October 18, 2013. Pet. Ex. 11 at 3. Medical records from multiple medical practitioners also consistently show petitioner reported receiving a flu vaccine in her left shoulder on October 18, 2013. For example, petitioner reported left arm pain after an October 18, 2013 flu shot to Dr. Veronica Mardo. Pet. Ex. 3 at 9, 72-74. Petitioner also reported to her physical therapist that the shoulder pain manifest following a flu shot in October of 2013. Pet. Ex. 4 at 1. Additionally, the petitioner also stated in her declaration that she received a flu vaccination in her left shoulder on October 18, 2013. Pet. Ex. 1 at ¶¶ 5-6.

For the above reasons, the undersigned finds that petitioner received a flu vaccination in her left shoulder on October 18, 2013, and that her pain and decreased range of motion are limited to her left shoulder.

d. No other condition or abnormality is present that would explain the patient’s symptoms

At the time of her October 23, 2013 flu vaccination and up to the date of November 2, 2015 when petitioner reported her shoulder was better, there does not appear to be any other condition or abnormality present that would explain the her left shoulder pain other than the vaccination.

e. Severity of Injury

The record also shows petitioner suffered “the residual effects or complications of [the injury] for more than 6 months after the administration of the vaccine” as is required under 45 U.S.C. § 300aa-11(c)(1)(D)(i). Petitioner stated she experienced immediate pain following the October 18, 2013 vaccination. Pet. Ex. 1 at 1. Pain was also reported in petitioner’s left shoulder on December 6, 2013, when she first sought medical care for her injury. Pet. Ex. 3 at 9. Petitioner reported that she had been experiencing pain since she received a vaccination on October 18, 2013. *Id.* Further, petitioner reported to Dr. Tedesco on November 20, 2014, left shoulder pain following her flu shot, and “[s]ince that time the shoulder has remained painful and now has gotten progressively weaker.” Pet. Ex. 3 at 68. The plain and clear meaning of the “progressive weakness” implies a weakness that arose and worsened over time. On

September 8, 2015, petitioner also reported a chronic history of left shoulder pain since a 2013 flu shot to Dr. Mighell at the Florida Orthopaedic Institute. Pet. Ex. 5 at 1. The medical records also indicate that petitioner was being treated for left shoulder pain until at least December 29, 2015 when, at a follow-up appointment for adhesive capsulitis in her left shoulder, she received a corticosteroid injection. *Id.* at 4.

Based on the totality of the medical records, the preponderant evidence shows the residual effects of petitioner's injury lasted for more than 6 months.

B. Medical Theory Causally Connecting the Vaccination and Injury

With regard to the *Althen* prongs, as discussed above, undersigned finds that petitioner has provided evidence sufficient to establish that she received the alleged vaccination, and that the vaccination caused her to suffer a SIRVA. Additional evidence related to causation includes petitioner's description of the vaccination as "given too high" in her left arm. Pet. Ex. 3 at 9. Improper administration of a vaccine, for example by injecting the vaccine too high in a patient's arm, is consistent with SIRVA found in other cases. A SIRVA resulting from improper vaccine administration is also consistent with the current rules, which state a SIRVA:

[M]anifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction.

42 C.F.R. § 100.3 (10).

C. A Logical Sequence of Cause and Effect

The undersigned also finds a logical sequence of cause and effect between petitioner's October 18, 2013 flu shot and the SIRVA. As explained above, petitioner described her injury as left shoulder pain that started after she received a flu shot, and "[s]ince that time the shoulder has remained painful" and got "progressively weaker." Pet. Ex. 3 at 68. Petitioner's shoulder pain was later described as starting after she received a flu shot in 2013, and chronic. Pet. Ex. 5 at 1.

The initial pain, and progressive nature of petitioner's injury, is consistent with a SIRVA, and shows a logical sequence of cause and effect between the October 18, 2013 flu shot and the later-reported SIRVA. Petitioner's progressive injury is also consistent with the proposed rule, which states a SIRVA includes "[c]linical signs of shoulder pain and restricted motion in the affected shoulder [that] appear shortly after vaccination." Rev. Vaccine Injury Table, 80 Fed. Reg. at 45,136.

The undersigned also finds that petitioner has established that she meets the severity requirement of the Vaccine Act by suffering from the residual effects of her injury for more than 6 months. 45 U.S.C. § 300aa-11(c)(1)(D)(i). As discussed above, petitioner experienced immediate pain following her October 18, 2013 flu vaccination. Pet. Ex. 1 at 1. Further, petitioner experienced residual effects of her injury until at least December 29, 2015 when, at a follow-up appointment for adhesive capsulitis in her left shoulder, she received a corticosteroid injection. *Id.* at 4.

D. A Proximate Temporal Relationship between Vaccination and Injury

The undersigned also finds a temporal relationship between petitioner's October 18, 2013 flu shot and the SIRVA. As stated above, petitioner consistently stated pain in her left shoulder started immediately after she received a flu shot on October 18, 2013. Pet. Ex. 2 at 1; Pet. Ex. 3 at 9, 72-74; Pet. Ex. 4 at 1. This is consistent with the interval of onset set forth in the Vaccine Table, which is within 48 hours of receiving a vaccination. 42 C.F.R. § 100.3. One issue identified by respondent is that the medical records do not document any complaints from petitioner about her shoulder until approximately six weeks after her October 18, 2013 flu vaccination. Res. Mot at 2. However, the medical records and affidavit evidence provide sufficient proof that petitioner's pain began immediately after her flu vaccination. As explained above, petitioner described her injury as left shoulder pain that started after she received a flu shot, and "[s]ince that time the shoulder has remained painful" and got "progressively weaker." Pet. Ex. 3 at 68. Petitioner's shoulder pain was also described as starting after she received a flu shot in 2013, and chronic. Pet. Ex. 5 at 1.

Petitioner's affidavit evidence supports the onset date of her shoulder pain. As cited above, petitioner's ex-husband, stated that petitioner began complaining of shoulder pain almost immediately after receiving her vaccination, and petitioner's former coworker also reported that petitioner complained of left shoulder pain that began "right after receiving the flu shot at a pharmacy." Pet. Ex. 10 at 1, Pet. Ex. 9 at 1.

The undersigned notes there are various consultations with medical professionals did not record shoulder pain. However, many of these visits were for specific ailments, such as respiratory infection, wherein neither a full physical nor muscular-skeletal exam occurred.⁵

Further, the records show periods of time when petitioner did not seek treatment for shoulder pain, including between December 6, 2013 and November 20, 2014, and again after December 30, 2014. Petitioner's reasons for the delay set forth in her affidavit, and gaps in her treatment, are credible and reasonable. Specifically, petitioner

⁵ For example, petitioner saw her gynecologist on February 24, 2014 (Pet. Ex. 3 at 16), an ear nose and throat specialist on May 8, 2014 (*id.* at 26) an allergy consultant on June 2, 2014 (*id.* at 30-33), and a dermatologist on November 4, 2014 (*id.* at 62-67). During these visits there is no mention of shoulder pain. However, it is not uncommon for patients seeing specialist not to mention ailments out of the specialists' specific purview.

described that she was unable to seek treatment for her shoulder pain until November 20, 2014, because she was the sole supporter of her family. Pet. Ex. 1 at 2. Petitioner also stated that she was unable to seek professional treatment after December 30, 2014, due to financial limitations and a serious medical issue involving her daughter that took priority over her shoulder. *Id.* This delay in seeking treatment was reasonable given the facts and circumstances, as are the gaps in petitioner's course of treatment.

V. Conclusion

In light of all of the above, and in view of the submitted evidence, including the medical records, credible witness affidavits, the undersigned finds that petitioner received a flu vaccination on October 18, 2013, and subsequently suffered a SIRVA. Petitioner also suffered the sequelae of the SIRVA for more than six months. Thus, petitioner is entitled to compensation.

IT IS SO ORDERED.

s/Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master